Influenza Vaccination Standard: Proposed Revisions to Medicare & Medicaid CoP

At a Glance

The Issue:
On May 4, the Centers for Medicare & Medicaid Services (CMS) issued a proposed rule that would revise the Medicare and Medicaid Conditions of Participation (CoP) to require hospitals, critical access hospitals and other facilities to offer all inpatients and outpatients an annual influenza vaccination. Specifically, CMS would require hospitals to develop and implement policies and procedures to offer annual vaccination for seasonal influenza and pandemic influenza. Within its policies and procedures, the hospital would be required to ensure that:

- Patients receive education on the benefits, risks and potential side effects of the vaccine.
- Each patient is offered vaccination annually from the time the vaccine is available on or after September 1 through the end of February of the following year, unless the patient has medical contraindications or has already been vaccinated.
- Patients have the opportunity to decline vaccination.
- Patients' health records include certain documentation.

Comments on the proposed rule are due to CMS by July 5. The agency plans to publish the final rule in early fall in time for it to become effective for the 2011-2012 influenza season.

Our Take:
The AHA agrees that increasing the number of individuals who receive the annual influenza vaccination is a key factor in decreasing the morbidity and mortality rates from influenza. However, the ideal location for individuals to receive influenza vaccination is in their primary care physician’s office or through the local public health department. While this is not always possible or practical, particularly for uninsured individuals, we are concerned that CMS’ proposal is essentially an unfunded mandate for hospitals in the midst of a difficult economic climate. We also believe that using the CoP to impose this requirement is unnecessarily heavy-handed in that enforcement may result in hospitals being terminated from the Medicare and Medicaid programs. The agency also makes no reference to liability, including potential coverage under the National Vaccine Injury Compensation Program. Further, the rule would be difficult to implement, particularly in time for the 2011-2012 seasonal influenza season. The AHA is gathering additional feedback from members on the proposed rule and will submit comments to CMS that address the field’s concerns and make recommendations to improve the standard.

What You Can Do:

- Share this advisory with your senior management, senior leader for quality, infection control professionals, pharmacy director, purchasing director, clinic managers, nurse managers and key physician leaders.
- Consider submitting comments to CMS before July 5 addressing the impact that the proposed rule will have on your hospital and its patients.

Further Questions:
Please contact Roslyne Schulman, director for policy, at rschulman@aha.org or Lisa Grabert, senior associate director for policy, at lgrabert@aha.org.

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AHA’s Regulatory Advisories are produced whenever there are significant regulatory developments that affect the job you do in your community. A four-page, in-depth examination of this issue follows.
Influenza Vaccination Standard: Proposed Revisions to Medicare & Medicaid CoP

BACKGROUND

The Centers for Medicare & Medicaid Services (CMS) published in the May 4 Federal Register a proposed rule that would revise the Medicare and Medicaid Conditions of Participation (CoP) to require hospitals (including short-term acute care, psychiatric, rehabilitation, long-term care, children’s and cancer hospitals), critical access hospitals (CAHs) and certain other facilities to offer all inpatients and outpatients an annual influenza vaccination, unless vaccination is medically contraindicated or the patient has already been vaccinated. Compliance with the CoP is required in order for hospitals and CAHs to participate in, and be reimbursed by, the Medicare and Medicaid programs. Failure to comply with the CoP can result in hospitals being terminated from these programs.

The rule is available at http://www.gpo.gov/fdsys/pkg/FR-2011-05-04/pdf/2011-10646.pdf. Comments on the proposed rule are due to CMS by July 5. The agency plans to publish the final rule in early fall so that the rule becomes effective in time for the 2011-2012 influenza season.

AT ISSUE

JUSTIFICATION

CMS estimates that the economic cost to society of seasonal influenza is roughly $87 billion each year, including more than $10 billion in direct medical costs. However, less than 40 percent of the population received an influenza vaccination during the 2008-2009 influenza season. Noting that the Centers for Disease Control and Prevention (CDC) now recommends that all individuals age 6 months and older receive annual influenza vaccinations, CMS argues there are missed opportunities for vaccinating individuals, including opportunities to vaccinate patients who are in hospitals and other care settings for other causes. CMS notes that in the first year that the agency required nursing homes to offer all residents an annual influenza vaccination, the vaccination rate of nursing home residents reached 90 percent.

In a discussion of health disparities, CMS states that influenza vaccination rates remain low among some minority populations. The agency believes that expanding access to influenza vaccination through this proposed rule would help address the needs of
vulnerable populations and diminish health disparities. CMS specifically requests comments on how it could strengthen the proposed CoP requirements to address disparities.

**PROVISIONS OF THE PROPOSED COP**

The proposed new CoP would require hospitals of all types (including short-term acute care, psychiatric, rehabilitation, long-term care, children’s and cancer), CAHs, rural health clinics, federally qualified health centers and end-stage renal disease facilities to offer all inpatients and outpatients (Medicare and Medicaid as well as non-Medicare and non-Medicaid) an annual influenza vaccination, unless vaccination is medically contraindicated or the patient has already been vaccinated.

In supporting this requirement, CMS states that these providers have in common two key factors: (1) In each setting, the patients present before health care providers with staff licensed to provide vaccination at the time and location of the encounter; and (2) all have ready access to equipment and storage appropriate for handling, controlling and administering vaccines.

The provisions of the proposed CoP would require hospitals and the other specified facilities to develop and implement policies and procedures to offer annual vaccination for seasonal influenza and pandemic influenza. Pandemic procedures would be implemented only when a pandemic event was announced by the Secretary of Health and Human Services. The policies and procedures would need to reflect the recommendations of nationally recognized experts (e.g., CDC or the American Academy of Pediatrics), including, but not limited to, guidelines addressing patients for whom vaccination may be prioritized or temporarily contraindicated.

Within its policies and procedures, the hospital would be required to ensure (subject to the reasonable availability of vaccine and taking into account the condition of each patient) all of the following:

- Before receiving the vaccination, each patient (or, as appropriate, the patient’s representative or surrogate) receives education regarding the benefits, risks and potential side effects of the vaccine. The patient also would have the choice of using an interpreter of his or her own choosing or one supplied by the hospital.

- Each patient is offered vaccination annually from the time the vaccine is available on or after September 1 through the end of February of the following year, except when such vaccination is medically contraindicated or when the patient has already been vaccinated during this time period.

- The patient (or the patient’s representative or surrogate) has the opportunity to decline vaccination.

- The patient’s health record includes documentation that indicates, at a minimum:
  - the date the patient (or the patient’s representative or surrogate) was provided education regarding the benefits, risks and potential side effects of vaccination; and
the date the patient either received the vaccination or did not receive it due to medical contraindications, previous vaccination during the time period or patient refusal.

In the event of a vaccine shortage, CMS would not require providers to offer vaccination if they were unable to obtain vaccine supplies. However, CMS would expect providers to make timely efforts to acquire the vaccine and to comply with guidance issued by CDC regarding priority groups for vaccination.

CMS emphasizes that hospitals’ policies and procedures should address all patients, regardless of whether they receive inpatient or outpatient services. However, the agency acknowledges that hospitals often have large outpatient populations, including patients visiting departments (such as physical therapy clinics) that are not necessarily prepared to provide vaccine injections. In that case, CMS states that it might be appropriate to refer certain outpatients to another clinic or department on the hospital campus for vaccination.

Although the proposed rule would require hospitals to inform patients of the risks, benefits and side effects of vaccination and would allow patients to decline, CMS includes no explicit discussion of liability issues around vaccination. Further, the proposed rule does not explicitly address payment for influenza vaccination. However, in its impact analysis, as noted below, CMS does presume that hospitals and CAHs will bill the patients’ health insurance plans for vaccination services if vaccination is covered under the patients’ health insurance plans. Medicare pays separately for vaccinations that are furnished to beneficiaries in hospital outpatient departments under the outpatient prospective payment system (PPS). For Medicare beneficiaries who are inpatients, there would be no additional payment for vaccination, beyond the MS-DRG payment under the inpatient PPS.

**IMPACT ANALYSIS**

CMS’ proposed rule is considered to be “economically significant” with associated overall costs of about $330 million annually but with overall quantifiable benefits of about $830 million annually, reflecting decreased medical care costs ($710 million) and savings in patient time ($120 million).

CMS estimates that it would take five hours annually to create and update vaccination policies and procedures in 5,100 hospitals, resulting in an annual cost of approximately $1.1 million (including $0.3 million for CAHs). CMS further assumes that approximately 20 million patients in hospitals will receive education/counseling and will require medical record documentation. Using CMS’ assumptions, the total annual cost for patient education would be $45 million and $9 million for medical record documentation. Further, CMS assumes that as a result of the proposed rule, approximately 8 million additional patients in hospitals will be vaccinated, resulting in a total cost of $36 million for administering the vaccine in hospitals and $144 million for the vaccine itself. Therefore, the total estimated cost of the proposed rule for hospitals would be approximately $235 million.
CMS’ Estimate of Annual Cost Impact on Hospitals

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<th>Requirement</th>
<th>Incremental burden</th>
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<th># of hospitals</th>
<th>Total annual burden (hours)</th>
<th>Total annual cost*</th>
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<td>Policies and Procedures</td>
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<td>5,100</td>
<td>25,500</td>
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<tr>
<td>CAH Policies and Procedures</td>
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<td>Cost of Vaccine**</td>
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<td>$144,000,000</td>
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<td><strong>TOTAL COST</strong></td>
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<td></td>
<td><strong>$235,147,500</strong></td>
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</tbody>
</table>

*$45 per hour for all labor rates  **$18 per vaccine dose

With regard to the net impact on hospitals and other providers/suppliers, CMS believes that the proposed rule will have little consequential adverse impact on provider costs, net of insurance reimbursement. CMS estimates that the proposed rule would impose gross costs of about $330 million annually on affected providers and suppliers, with almost all vaccine costs and at least half of all other costs (totaling $240 million) reimbursed through third party payments. This would leave a net cost impact on providers of about $90 million.

**NEXT STEPS**

The AHA will be submitting comments to CMS and encourages members also to submit comments outlining how the agency’s proposal will affect their facilities and patients. Comments are due by July 5 and may be submitted electronically at http://www.regulations.gov. Follow the instructions for “Comment or Submission.” You may use Microsoft Word, WordPerfect or Excel; however, CMS prefers Microsoft Word.

CMS also accepts written comments (an original and two copies) via regular or overnight/express mail.

**Via regular mail:**
Centers for Medicare & Medicaid Services
Dept. of Health and Human Services
Attention: CMS-3213-P
P.O. Box 8010
Baltimore, MD 21244-1850

**Via overnight or express mail:**
Centers for Medicare & Medicaid Services
Dept. of Health and Human Services
Attention: CMS-3213-P
Mailstop: C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

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